K082417

OCT 21 2008

## 6 510(k) Summary

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| **Submitter:** | ARKRAY Factory USA, Inc<br><br>Est. Number: 1832816<br>Owner/Operator Number: 8030316 |
| **Contact Person:** | Tom Speikers<br>Director, Quality Systems and Regulatory Affairs<br>ARKRAY Factory USA, Inc.<br>5182 W. 76th Street<br>Minneapolis, MN 55439<br>Phone: 952-646-3168<br>Fax: 952-646-3110<br>speikerst@arkrayusa.com |
| **Date Prepared:** | August 20, 2008 |
| **Trade Name:** | GLUCOCARD™ 01-mini Blood Glucose Monitoring System |
| **Classification:** | Glucose test system, 21 CFR 862.1345, Class II |
| **Product Codes:** | CGA, NBW, JJX |
| **Predicate Device:** | ARKRAY GLUCOCARD™ 01 Blood Glucose Monitoring System |
| **Device Description:** | GLUCOCARD™ 01-mini consists of a meter, test strips, and control solutions for use in measuring blood glucose as an aid to monitor the effectiveness of diabetes control. |
| **Intended Use:** | The GLUCOCARD™ 01-mini Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. |
| **Functional and Safety Testing:** | A clinical study was done with persons with diabetes to evaluate system accuracy and to assess ease of use.<br><br>Analytical verification testing was performed to evaluate precision, dynamic range and linearity. |
| **Conclusion:** | The modified GLUCOCARD™ 01-mini Blood Glucose Monitoring System is substantially equivalent to the predicate GLUCOCARD™ 01 Blood Glucose Monitoring System. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

ARKRAY Factory USA, Inc.
c/o Tom Speikers
Director, Quality Systems and Regulatory Affairs
5182 W. 76th Street
Minneapolis, MN 55439

OCT 21 2008

Re: K082417
Trade/Device Name: GLUCOCARD™ 01-mini Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, NBW, JJX
Dated: September 18, 2008
Received: September 22, 2008

Dear Mr. Speikers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# 5 Indications for Use Statement

510(k) Number (if known): K082417

Device Name: ARKRAY GLUCOCARD™ 01-mini Blood Glucose Monitoring System

Indication For Use:

GLUCOCARD™ 01-mini Blood Glucose Monitoring System:
The GLUCOCARD™ 01-mini Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

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| Prescription Use _____ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use ____X____ (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K082417